

**CLAIMS:**

1. A composition having a viscosity of 150cp or less at 25°C and comprising (i) chitosan, a salt or derivative thereof or a salt of a derivative thereof, (ii) a polyol-phosphate or sugar-phosphate salt, (iii) a plasticizer, and (iv) a therapeutic agent.  
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2. The composition according to claim 1 in the form of an aqueous solution or suspension.  
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3. The composition according to claim 1, which forms a gel at a temperature 30 °C or greater.  
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4. The composition according to claim 3, which forms a gel in 15 minutes or less at a temperature of from 30 to 40 °C.  
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5. The composition according to claim 4, which forms a gel in 15 minutes or less at a temperature of from 35 to 37 °C.  
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6. The composition according to claim 1, wherein the plasticizer is triethyl citrate.  
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7. The composition as claimed in claim 1, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof has a molecular weight of 4000 Dalton or greater.  
7. The composition according to claim 1, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof has a molecular weight of 4000 Dalton or greater.  
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8. The composition according to claim 7, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof, has a molecular weight of from 50,000 to 300,000 Dalton.  
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9. The composition according to claim 1, comprising chitosan base or a chitosan derivative that has been formed by bonding of acyl or alkyl groups with the hydroxyl groups of the chitosan or a nitrate, phosphate, sulphate, citrate, hydrochloride, glutamate, lactate or acetate salt of chitosan.

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10. The composition according to claim 1, wherein the chitosan has a degree of deacetylation of 40 % or greater.

10 11. The composition according to claim 12, wherein the degree of deacetylation is from 70 to 90 %.

12. The composition according to claim 1, comprising from 0.25 to 3.0 % w/v of chitosan, a salt or a derivative thereof or a salt of a derivative thereof expressed as chitosan base.

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13. The composition according to claim 12 comprising from 0.45 to 1.5 %w/v of chitosan, a salt or a derivative thereof or a salt of a derivative thereof expressed as chitosan base.

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14. The composition according to claim 1, wherein the therapeutic agent is present in solution or as a suspension.

15. The composition according to claim 1, wherein the polyol-phosphate salt is  $\beta$ -glycerophosphate disodium.

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16. The composition according to claim 1, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.25 to 3.0 % w/v.
- 5 17. The composition according to claim 16, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.75 to 2.0 % w/v.
- 10 18. The composition according to claim 1, comprising from 0.05 to 5.0 % w/v of the plasticizer.
19. The composition as claimed in Claim 18 comprising from 0.2 to 1.0 % w/v of the plasticizer.
- 15 20. The composition according claim 1, additionally comprising ascorbic acid.
21. The composition according to claim 20 comprising from 0.01 to 0.2 % w/v ascorbic acid.
- 20 22. The composition according to claim 1, wherein the therapeutic agent is a polar drug, a polypeptide, a gene or a gene construct.
23. The composition according to claim 22, wherein the therapeutic agent is insulin, calcitonin, leuprolide, luteinising hormone releasing hormone, growth hormone or a growth hormone releasing factor, naratriptan, sumatriptan, zolmitriptan, rizatriptan, eletriptan, frovatriptan, alnitiidan, avitriptan, almotriptan, apomorphine, sildenafil,

alprostadil, diamorphine, hydromorphone, buprenorphine, fentanyl, oxycodone, codeine, morphine or morphine-6-glucuronide.

24. A drug delivery device suitable for delivery of a composition via one or more of the nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular routes or a dose cartridge for use with such a device loaded with a composition as defined in claim 1.
25. A process for the preparation of the composition as defined in claim 1, which process comprises mixing a solution comprising chitosan or a salt or derivative thereof or a salt of a derivative thereof with a solution comprising a polyol-phosphate or sugar-phosphate salt.
26. The use of the combination of chitosan or a salt or derivative thereof or the salt of a derivative thereof, a polyol-phosphate or sugar-phosphate salt and a plasticizer in the manufacture of a medicament for use in the transport of a therapeutic agent across a mucosal surface in an animal.
27. The use of the combination of chitosan or a salt or derivative thereof or the salt of a derivative thereof, a polyol-phosphate or sugar-phosphate salt and a plasticizer in the manufacture of a medicament for nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery.
28. The use of a composition as defined in claim 1, in the manufacture of a medicament for use in the transport of a therapeutic agent across a mucosal surface in an animal.

29. The use of a composition as defined in claim 1, in the manufacture of a medicament for nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery.
- 5       30. The use according to claim 26, wherein the medicament is intended for local action.
31. The use according to claim 26, wherein the medicament is intended for systemic action.

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32. The use of a composition as defined in claim 1, in the administration of a therapeutic agent for transport thereof across a mucosal surface in an animal.
- 15     33. The use of a composition as defined in claim 1, in nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery of a therapeutic agent to an animal.
34. The use according to claim 32, wherein the therapeutic agent is intended for local action.
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35. The use according to claim 32, wherein the therapeutic agent is intended for systemic action.